

REMARKS

Applicants express appreciation to the Examiner for the time spent with applicants' representatives discussing the proposed claim amendments and prior art. As presented herein for reconsideration, the claims have been amended as proposed. Specifically, claims 30, 33-38, and 40 have been amended,¹ claims 1 – 24 have been cancelled without prejudice, and claims 25 – 29 stand withdrawn as directed to a non-elected invention. Thus, by this paper, claims 30 and 32-40 remain pending, of which claims 30 and 40 are the independent claims.

Vascular closure devices are used to facilitate closure of a subcutaneous puncture site of a vessel. Traditional vascular closure methods include manual compression, suturing, plugs, and other techniques. Manual compression typically requires extended periods. Manual suturing typically requires considerable skill by the practitioner. Plugs may become dislodged into the vessel. Other mechanical occlusion devices may substantially protrude into the blood stream. In view of these problems applicants have developed a new device for sealing a subcutaneous puncture site of a vessel.

As presented herein for reconsideration (see independent claim 30, as exemplary), the claims are directed to a device for sealing a subcutaneous puncture site of a vessel where the subcutaneous puncture site is accessed through a puncture tract that extends through subcutaneous tissue to the subcutaneous puncture site. The device is comprised of a first disk having a membrane made of material that is flexible and fluid impermeable, and a self-expanding wire frame which supports the membrane. The membrane and wire frame are foldable into a first configuration wherein the disk is folded to permit introduction of the folded disk through the puncture tract of the tissue to the subcutaneous puncture site, and then through the subcutaneous puncture site into the interior of the vessel. The membrane and wire frame are self-expanding toward a second configuration once inside the vessel in order to unfold so that the membrane and wire frame will position the disk against the interior wall of the subcutaneous puncture site to facilitate sealing of the puncture site.

The device is further defined as comprising a second disk moveably connected to the wire frame of the first disk prior to and throughout deployment so as to advance together as an integral unit through the puncture tract, the second disk being configured for placement within

¹ Any amendments to claims other than those which are expressly relied upon in overcoming the rejections on art have been made simply to insure consistency in claim language to correct typographical or grammatical errors, or to correct other errors of a formal, non-substantive nature, but not to otherwise narrow the claims in scope for any reason.

the puncture tract to securely engage the tissue of the puncture tract, and when secured within the puncture tract the second disk exerting a lateral force on the surrounding tissue of the puncture tract and exerting a longitudinal force on the first disk when it is unfolded in order to urge the first disk against the puncture site to facilitate sealing the puncture site. The second disk has a self-expanding wire frame foldable into a first configuration wherein the second disk is folded to permit introduction of the folded second disk and the folded first disk through the puncture tract of the tissue to the subcutaneous puncture site, and then introduction of the first disk through the subcutaneous puncture site into the interior of the vessel, with the wire frame of the second disk then being self-expanding toward a second configuration once inside the puncture tract in a second configuration so that the wire frame of the second disk will exert a lateral force on the surrounding tissue of the puncture tract while also exerting a longitudinal force against the first disk in order to urge the first disk against the interior wall of the subcutaneous puncture site to facilitate sealing of the puncture site. The first disk and the second disk are also separated by a first distance in the first configuration and by a second distance in the second configuration, the first distance being larger than the second distance.²

In the Office Action, independent claims 30 and 40 were rejected as being obvious over U.S. Pub. No. 2003/0055455 (Yang) in view of U.S. Pat. No. 7,431,729 (Chanduszko).^{3 4} As discussed in the interview, and as presented herein for reconsideration, independent claims 30 and 40 and their depending claims are neither anticipated nor made obvious by Yang and

² Independent claim 40 is similar. Claim 40 differs from claim 30 by adding a further limitation that requires that the second disk is moveably connected “to facilitate repositioning of the device at the subcutaneous puncture site” and by removing the limitation that “the first disk and the second disk [are] separated by a first distance in the first configuration and by a second distance in the second configuration, the first distance being larger than the second distance.”

³ Since both Yang and Chanduszko qualify as “prior” art, if at all, under 35 U.S.C. 102(e), applicants reserve the right to challenge the status of either or both references as qualifying “prior” art. Accordingly, any statement or comment herein to Yang or Chanduszko is made merely for purposes of argument, and merely assumes *arguendo* that those references are qualifying prior art.

⁴ The dependent claims were rejected as obvious over Yang in view of Chanduszko and further in view of Shaw, Stevens, and/or Van Tassel. While the arguments herein are focused on the differences between the independent claims and the prior art of record, which differences are equally applicable to the dependent claims, this does not mean that these are necessarily the *only* differences between the claimed invention and the prior art of record. Applicants thus do not acquiesce in any asserted rejections of the dependent claims. Nothing in the remarks is intended to constitute, and should not be construed as, an acquiescence on the part of applicants as to the purported teachings or prior art status of the cited references, as to the characterization of the cited references advanced by the Examiner, or as to any other assertions, allegations or characterizations made by the Examiner. Applicants reserve the right to challenge the purported teaching of the cited references or any judicial notice asserted at any appropriate time.

Chanduszko, either singly or in combination with any other prior art of record, and thus favorable reconsideration is respectfully requested.

Yang is concerned with systems and methods for treating septal defects in a heart (e.g. a hole that may exist in a wall of the heart). Yang (see Figs. 1 and 4) includes a first catheter and a second catheter that may be introduced through separate chambers of the heart to opposite sides of the heart wall, where the hole or septal defect is located. Using a bridge member to align the two catheters across the heart wall, the first and second catheters are then used to separately deliver a patch to each side of the wall so that the hole is patched from both sides of the heart wall. The two patches (one from the first catheter and one from the second catheter) are then urged together and connected across the septal defect.

Note, however, that unlike applicants’ claimed device, Yang does not provide “a first disk having a membrane made of material that is flexible and fluid impermeable, and a self-expanding wire frame which supports the membrane . . . [and] a second disk *moveably connected to the wire frame of the first disk prior to and throughout deployment so as to advance together as an integral unit through the puncture tract*, the second disk being configured for placement within the puncture tract to securely engage the tissue of the puncture tract, and when secured within the puncture tract *the second disk exerting a lateral force on the surrounding tissue of the puncture tract and exerting a longitudinal force on the first disk when it is unfolded* in order to urge the first disk against the puncture site to facilitate sealing the puncture site.” (Claims 30 and 40, emphasis added). Yang’s introduction of first and second catheters into chambers on opposite sides of a heart wall for separate placement of a patch on side of the wall is completely unlike applicants’ claimed device.

Like Yang, Chanduszko is also concerned with a device for occluding a septal defect. As described, the distal side 30 and proximal side 40 of the occluder (see for example Figs. 14A – 14E) are connected by intermediate joint 22 (a weld, solder, tube, or spring). The intermediate joint 22 secures the distal and proximal sides 30,40. The occluder is introduced through a catheter 140 so that joint 22 is positioned across the septal defect 18 of the heart wall (Fig. 14B), and the distal side 30 of the occluder is then released from the catheter 140 (Fig.14C). Catheter 140 is then withdrawn to the other side of the septal defect (Fig. 14D) and distal side 40 is then released (Fig. 14E), covering the other side of the defect.

In contrast to applicants’ claimed device, Chanduszko does not provide “a second disk *moveably connected to the wire frame of the first disk prior to and throughout deployment so as to advance together as an integral unit through the puncture tract and to facilitate repositioning*

of the device at the subcutaneous puncture site, the second disk being configured for placement within the puncture tract to securely engage the tissue of the puncture tract, and when secured within the puncture tract the second disk exerting a lateral force on the surrounding tissue of the puncture tract and exerting a longitudinal force on the first disk when it is unfolded in order to urge the first disk against the puncture site to facilitate sealing the puncture site.” (Claim 40, emphasis added).

Nor does Chanduszko teach or suggest “a second disk *moveably connected to the wire frame of the first disk prior to and throughout deployment* so as to advance together as an integral unit through the puncture tract, . . . and *the first disk and the second disk being separated by a first distance in the first configuration [e.g. prior to deployment] and by a second distance in the second configuration [e.g. after deployed], the first distance being larger than the second distance.”*

Stevens was cited as a secondary reference, and is also concerned with devices for closing a septal defect in a heart wall with either sutures or with patch-type devices. Specifically, Stevens focuses on reducing the difficulty of manipulating artificial patches into position across a septal defect and improving fixation of the patches to prevent migration or embolization of the patches. The artificial patches include a proximal patch and a distal patch that are connected.

Like Chanduszko, Stevens introduces the patches for each side of the heart wall through a catheter 22 (see Figs. 15 – 16). The distal patch 144 is placed on one side of the septal defect using an outer control rod 134 (Fig. 15) and the proximal patch 164 (Fig. 16) is then placed on the other side of the septal defect using an inner control rod 138. The distal patch 144 and proximal patch 164 are connected in a snap fit relationship after they are positioned over the septal defect. Figs. 21 – 24 show proximal and distal patches attached together by attachment means such as a ring at the center of the patches, or a single suture in a circular running stitch, a plurality of individual knotted suture loops, rivets, or other fasteners, or a circular series of continuous lines of adhesive bonding or heat welding.

However, like the other references noted, Stevens contains no teaching or suggestion as to either “a second disk *moveably connected to the wire frame of the first disk prior to and throughout deployment* so as to advance together as an integral unit through the puncture tract and to facilitate repositioning of the device at the subcutaneous puncture site, the second disk being configured for placement within the puncture tract to securely engage the tissue of the puncture tract, and when secured within the puncture tract the second disk exerting a lateral

force on the surrounding tissue of the puncture tract and exerting a longitudinal force on the first disk when it is unfolded in order to urge the first disk against the puncture site to facilitate sealing the puncture site,” (Claim 40, emphasis added), or as to “a second disk moveably connected to the wire frame of the first disk prior to and throughout deployment so as to advance together as an integral unit through the puncture tract, . . . and the first disk and the second disk being separated by a first distance in the first configuration [e.g. prior to deployment] and by a second distance in the second configuration [e.g. after deployed], the first distance being larger than the second distance.” (Claim 30, emphasis added).

For at least the reasons noted,⁵ independent claims 30 and 40 are patentable over the prior art of record. Indeed, as noted in the Interview Summary prepared by the Examiner at the interview’s conclusion, “Proposed independent claims . . . 30 and 40 of the parent [i.e. the present application] . . . appear to define over the art of record.” Thus, favorable reconsideration and allowance is respectfully requested.⁶

In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

⁵ The other references of record, while briefly discussed at the interview, were readily acknowledged as being of much less relevance than the references noted and discussed above.

⁶ As discussed at the interview applicants have also submitted with this response a terminal disclaimer relative to the other two related applications discussed at the interview.

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Supplemental Amendment "F"

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Respectfully submitted,

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